Independent Reviewers of Texas

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Notice of Independent Review Decision

IRO REVIEWER REPORT TEMPLATE – HC

[Date notice sent to all parties]:

8/17/2015 and 8/31/2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: L5 Gill Laminectomy L5-S1 transforaminal lumbar interbody fusion and posterior fusion with 2 days length stay.

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION: Board Certified Orthopedic Surgeon

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

X Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]: The patient is a male who reported an injury on xx/xx/xx. His mechanism of injury was stated as he was involved in a motor vehicle accident, whereupon he was struck from the side and injured his neck and lower back. The patient was initially diagnosed with degenerative lumbar or lumbosacral intervertebral disc disease with lumbosacral neuritis or radiculitis unspecified as of xxxx. The patient was provided with Flexeril and was sent to physical therapy to begin rehabilitation toward treatment of both his low back and cervical issues. The physical therapy outpatient progress report/reassessment dated xxxx indicated the patient had a further diagnosis of degenerative disc disease in the lumbar region with post-laminectomy and lumbar radiculopathy. As of xxxx, the patient had developed foot drop in the right lower extremity. He also indicated that his low back pain had increased and he was

taking MS ER at bed, though not every night. When the patient was seen on xxx, he was restarting his physical therapy due to right leg weakness. MRI from xxxx showed a herniation at L5-S1. As of xxxx, the patient's physical therapy had ended as of xxxxx. The provider stated the patient had “back slip” with the patient having undergone a previous epidural steroid injection a year prior, which had helped for several weeks. The patient continued to have a positive straight leg raise on the right at 75 degrees and pain with seated straight leg raise located at the back and buttocks. Right light touch was abnormal at the L5 and S1 dermatomes with current right gastrocsoleus strength rated as 4/5. The patient underwent a right L5 transforaminal epidural steroid injection on xxxx. The patient stated that the injection helped for only 1 day with the anesthetic phase but nothing for the corticosteroid phase. His pain level went from a 7 to a 4 and his blood sugar only went to 175, which was better. By xxxx, the patient had a 70 pound weight loss and although his upper extremity symptoms had resolve with some residual left arm pain, his worst pain was located in his low back and bilateral lower extremities. He had been utilizing a cane for the past year with x-rays reviewed from AP flexion and extension lumbar x-rays identifying spondylolisthesis at L5-S1 with lytic grade 1. An MRI of the lumbar spine was performed on xxxx which noted at the L4-5 level was minimal disc bulging with no focal protrusion or central stenosis, with some disc osteophyte encroachment resulting in mild to moderate bilateral neural foraminal stenosis or worsening on the left. At L5-S1 was a broad based disc bulge with a small more focal central protrusion. There was contact of the thecal sac without significant deformity and no significant central stenosis, with disc osteophyte encroachment resulting in moderate bilateral neural foraminal stenosis. The impression identified bilateral pars defects at L5. The patient was seen again on xxxx for possible lumbar surgery evaluation. The patient had gradually increasing back and bilateral leg symptoms over the past year with pain and numbness in his buttock and posterior thigh into his lateral calf, anterior knee, anterior lower leg, and top of his foot, worse on the right than the left. Symptoms were worse with standing and walking, with the patient getting relief by sitting and flexing his hips, knees, and lumbar spine. The patient had had a total of more than xxxx months of physical therapy in xxxx and xxxx, including land based therapy and aquatic therapy. The most recent office visit, dated xxxx, was an appeal letter to the prior adverse determination, stating that the patient's physical examination noted objective documentation of weakness in the right leg with grade 2/5 strength in the right ankle dorsiflexion and EHL with diminished sensation on the right in the L5 distribution. The physician further stated the patient had failed lower levels of care, including prior injections, medications, and physical therapy, and also had an 80 pound weight loss and failure of use of a cane, and has indicated that the patient would meet the Official Disability Guidelines; criteria for undergoing the requested surgical procedures.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION: The requested service was previously denied on xxxx due to a lack of evidence of instability on x-rays noting instability of greater than 4.5 mm and no objective documentation of radiculopathy noted on physical examination. At the time, there was no failure of lower levels of care, including prior injections, oral medications, or progress notes from formal physical therapy. A second adverse determination was provided, dated 06/26/2015, which stated that again, there was no radiographic evidence of significant instability of greater than 4.5 mm as recommended by the guidelines on flexion and extension x-rays

provided as required. While there was reference to AP flexion and extension lumbar x-rays from xxxxx, indicating the patient had spondylolisthesis of L5-S1 with lytic grade 1, there was still no documentation of lumbar intersegmental translational movement of more than 4.5 mm as required in the Official Disability Guidelines. Additionally, multiple physical therapy outpatient progress report/reassessment notes, with the most recent identified as xxxxx, listed under the therapy diagnosis that the patient had ICD code 722.52 for degenerative disc disease – lumbar/"lumbar postlaminectomy, lumbar" with no clarification if this patient had undergone a prior laminectomy procedure. Therefore, with the physician failing to have addressed the previous adverse determination issue and no confirmation of whether or not this patient had undergone a prior laminectomy in the lumbar region and at what levels, the current request for an L5 Gill laminectomy L5-S1 transforaminal lumbar interbody fusion and posterior fusion with 2 days' length of stay cannot be supported. Therefore, although the patient has had failure of conservative modalities and was cleared from a psychological standpoint, without meeting all of the guideline criteria for the requested surgical procedure and without confirmation a potential prior laminectomy at the lumbar level, the requested service is not considered standard of care. Therefore, in agreement with the previous determination, the requested service is non-certified.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

[x] ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

REFERENCES:

Official Disability Guidelines (ODG), Treatment Index, 11th Edition (web), 2015, Low Back Chapter, Discectomy/ laminectomy, Fusion (spinal), Hospital length of stay (LOS).

ODG Indications for Surgeryä -- Discectomy/laminectomy --

Required symptoms/findings; imaging studies; & conservative treatments below:

I. Symptoms/Findings which confirm presence of radiculopathy. Objective findings on examination need to be present. Straight leg raising test, crossed straight leg raising and reflex exams should correlate with symptoms and imaging.

Findings require ONE of the following:

A. L3 nerve root compression, requiring ONE of the following:

1. Severe unilateral quadriceps weakness/mild atrophy
2. Mild-to-moderate unilateral quadriceps weakness
3. Unilateral hip/thigh/knee pain

B. L4 nerve root compression, requiring ONE of the following:

1. Severe unilateral quadriceps/anterior tibialis weakness/mild atrophy
2. Mild-to-moderate unilateral quadriceps/anterior tibialis weakness
3. Unilateral hip/thigh/knee/medial pain

C. L5 nerve root compression, requiring ONE of the following:

1. Severe unilateral foot/toe/dorsiflexor weakness/mild atrophy

2. Mild-to-moderate foot/toe/dorsiflexor weakness

3. Unilateral hip/lateral thigh/knee pain

D. S1 nerve root compression, requiring ONE of the following:

1. Severe unilateral foot/toe/plantar flexor/hamstring weakness/atrophy

2. Moderate unilateral foot/toe/plantar flexor/hamstring weakness

3. Unilateral buttock/posterior thigh/calf pain

(EMGs are optional to obtain unequivocal evidence of radiculopathy but not necessary if radiculopathy is already clinically obvious.)

II. Imaging Studies, requiring ONE of the following, for concordance between radicular findings on radiologic evaluation and physical exam findings:

A. Nerve root compression (L3, L4, L5, or S1)

B. Lateral disc rupture

C. Lateral recess stenosis

Diagnostic imaging modalities, requiring ONE of the following:

1. MR imaging

2. CT scanning

3. Myelography

4. CT myelography & X-Ray

III. Conservative Treatments, requiring ALL of the following:

A. Activity modification (not bed rest) after patient education (>= 2 months)

B. Drug therapy, requiring at least ONE of the following:

1. NSAID drug therapy

2. Other analgesic therapy

3. Muscle relaxants

4. Epidural Steroid Injection (ESI)

C. Support provider referral, requiring at least ONE of the following (in order of priority):

1. Physical therapy (teach home exercise/stretching)

2. Manual therapy (chiropractor or massage therapist)

3. Psychological screening that could affect surgical outcome

4. Back school (Fisher, 2004)

For average hospital LOS after criteria are met, see Hospital length of stay (LOS).

Patient Selection Criteria for Lumbar Spinal Fusion:

(A) Recommended as an option for the following conditions with ongoing symptoms, corroborating physical findings and imaging,

and after failure of non-operative treatment (unless contraindicated e.g. acute traumatic unstable fracture, dislocation, spinal cord injury) subject to criteria below:

(1) Spondylolisthesis (isthmic or degenerative) with at least one of these:

(a) instability, and/or

(b) symptomatic radiculopathy, and/or

(c) symptomatic spinal stenosis;

(2) Disc herniation with symptomatic radiculopathy undergoing a third decompression at the same level;

(3) Revision of pseudoarthrosis (single revision attempt);

(4) Unstable fracture;

(5) Dislocation;

(6) Acute spinal cord injury (SCI) with post-traumatic instability;

(7) Spinal infections with resultant instability;

(8) Scoliosis with progressive pain, cardiopulmonary or neurologic symptoms, and structural deformity;

(9) Scheuermann's kyphosis;

(10) Tumors.

(B) Not recommended in workers' compensation patients for the following conditions:

(1) Degenerative disc disease (DDD);

(2) Disc herniation;

(3) Spinal stenosis without degenerative spondylolisthesis or instability;

(4) Nonspecific low back pain.

(C) Instability criteria: Segmental Instability (objectively demonstrable) - Excessive motion, as in isthmic or degenerative spondylolisthesis, surgically induced segmental instability and mechanical intervertebral collapse of the motion segment and advanced degenerative changes after surgical discectomy, with relative angular motion greater than 15 degrees L1-2 through L3-4, 20 degrees L4-5, 25 degrees L5-S1. Spinal instability criteria includes lumbar inter-segmental translational movement of more than 4.5 mm. (Andersson, 2000) (Luers, 2007) (Rondinelli, 2008)

(D) After failure of two discectomies on the same disc [(A)(2) above], fusion may be an option at the time of the third discectomy, which should also meet the ODG criteria. (See ODG Indications for Surgery -- Discectomy.)

(E) Revision Surgery for failed previous fusion at the same disc level [(A)(3) above] if there are ongoing symptoms and functional limitations that have not responded to non-operative care; there is imaging confirmation of pseudoarthrosis and/or hardware breakage/malposition; and significant functional gains are reasonably expected. Revision surgery for purposes of pain relief must be approached with extreme caution due to the less than 50%

success rate reported in medical literature. Workers compensation and opioid use may be associated with failure to achieve minimum clinically important difference after revision for pseudoarthrosis (Djurasovic, 2011) There is low probability of significant clinical improvement from a second revision at the same fusion level(s), and therefore multiple revision surgeries at the same level(s) are not supported.

(F) Pre-operative clinical surgical indications for spinal fusion should include all of the following:

(1) All physical medicine and manual therapy interventions are completed with documentation of reasonable patient participation with rehabilitation efforts including skilled therapy visits, and performance of home exercise program during and after formal therapy. Physical medicine and manual therapy interventions should include cognitive behavioral advice (e.g. ordinary activities are not harmful to the back, patients should remain active, etc.);

(2) X-rays demonstrating spinal instability and/or myelogram, CT-myelogram, or MRI demonstrating nerve root impingement correlated with symptoms and exam findings;

(3) Spine fusion to be performed at one or two levels;

(4) Psychosocial screen with confounding issues addressed; the evaluating mental health professional should document the presence and/or absence of identified psychological barriers that are known to preclude post-operative recovery;

(5) For any potential fusion surgery, it is recommended that the injured worker refrain from smoking for at least six weeks prior to surgery and during the period of fusion healing; (Colorado, 2001) (BlueCross BlueShield, 2002)

(6) There should be documentation that the surgeon has discussed potential alternatives, benefits and risks of fusion with the patient;

(7) For average hospital LOS after criteria are met, see Hospital length of stay (LOS).

ODG hospital length of stay (LOS) guidelines:

Discectomy (icd 80.51 - Excision of intervertebral disc)

Actual data -- median 1 day; mean 2.1 days (± 0.0); discharges 109,057; charges (mean) $26,219

Best practice target (no complications) -- Outpatient

Laminectomy (icd 03.09 - Laminectomy/laminotomy for decompression of spinal nerve root)

Actual data -- median 2 days; mean 3.5 days (±0.1); discharges 100,600; charges (mean) $34,978

Best practice target (no complications) -- 1 day

Note: About 6% of discharges paid by workers' compensation.

Lumbar Fusion, posterior (icd 81.08 - Lumbar and lumbosacral fusion, posterior technique)

Actual data -- median 3 days; mean 3.9 days (±0.1); discharges 161,761; charges (mean) $86,900

Best practice target (no complications) -- 3 days

Note: About 15% of discharges paid by workers' compensation.